

**WASHINGTON STATE DEPARTMENT OF LABOR & INDUSTRIES
OFFICE OF THE MEDICAL DIRECTOR
TECHNOLOGY ASSESSMENT
INTRADISCAL HEATING TECHNIQUES**

1. Background

Intradiscal heating uses a needle or catheter, inserted into a herniated disc, to deliver controlled heat into the disc at a range of 65-80 Celsius. The purpose of intradiscal heating is to reduce discogenic pain in a minimally invasive way, via three specific actions. These actions are:

- The shrinkage of collagen fibers within a temperature range in which permanent damage does not occur and regrowth around the shortened fibers occurs;
- Cauterization of granulation tissue; and
- Thermocoagulation of nervous tissue.

Intradiscal heating methods depend on thermal energy to produce controlled tissue modification. These methods are supposed to be used in conjunction with safety parameters so that they do not lead to permanent tissue damage. Residual fibroblasts are intended to be left intact so that they repair the tissue by replacing denatured collagen with new collagen. The desired outcome of intradiscal heating is to achieve tissue shrinkage, which is maintained as the tissue heals and regains its mechanical properties.

There are two methods currently employed to deliver heat to a herniated disc which will be covered in this assessment, radiofrequency generated heat and electrically generated heat. Another method of shrinking collagen, laser disc decompression (LDD) enjoys some popularity in Europe but is not popular in the US, primarily due to a lack of control over the temperature that the laser generates. The kit that the manufacturer, Laserscope, sells does not include a computer delivery system like the RF and electrothermal methods employ.

Radiofrequency generated technique

The earliest method was developed in the early 1990's and employs radiofrequency (RF) generated heat. Radiofrequency controlled delivery systems include straight needle delivery method, a technique shown to be more promising on shoulders than on discs because exact placement is difficult. This technique is criticized primarily because of the lack of ability of the RF current to effectively reach therapeutic temperatures in the surrounding tissue. It is speculated that the effective heating radius is probably limited to 2 to 4 mm distances from the needle tip.

Radionics markets two devices for this procedure, a generator and needle. In their literature, they note that their founder, B. Cowman, first developed RF generator systems

in 1952. The generator that they market comes with a monitoring system that displays lesioning parameters and can be controlled by the medical provider.

According to rival manufacturer, Oratek, limitations of RF controlled delivery systems could include:

- tissue impedance limitations because RF heats better in a saline environment
- high temps which can char and burn tissue
- not as consistent an effect on collagen shrinkage
- smaller treatment area due to the actual needle (straight needle)
- poorer accessibility because needle cannot reach posterior wall.

Electrically generated technique

The newer method of intradiscal heating, electrically generated heat is Oratek's SpineCath, which employs a thermal resistive coil with a navigable hooked catheter. Called IDET, also known as intradiscal thermocoagulation or annuloplasty, heat is delivered at an ideal temperature of 65 Celsius to the disc nucleus and annular wall via the rounded catheter, for approximately 15 minutes. Oratek received 510 (k) status on March 19, 1998 for treatment of symptomatic patients with annular disruption of contained herniated discs.

Oratek's system utilizes a 17-gauge needle that a catheter is threaded through. The rounded catheter is inserted into the disc, with ideal placement in the outer posterior third of the disc, across the middling of the posterior wall and centered between the end plates. The catheter is then itself heated, spreading radiant heat into the surrounding tissue. This technique differs from radiofrequency, where heat is propelled through the cannulae into the disc. Treatment takes approximately 15 minutes and is performed under light sedation on an outpatient basis.

Oratek's Temperature Mapping Studies

Because the outcome is to achieve maximum tissue shrinkage without attendant destruction, an ideal range must be set into Oratek's computer delivery system. Though minimal, some research looking at ideal ranges has been done and has shown maximum shrinkage occurs in a range of 75 c to 80 c¹. Twenty-one cadaver samples were tested to determine heat dispersion in the lumbar disc and 10 patients with 15 discs. Using their SpineCath system and protocol, the maximum temperature reached in the cadavers was 76.8 Celsius and on live samples, 79.0 Celsius².

2. Why OMD is reviewing it

In December of 1998, two Washington physicians approached the department requesting coverage. One is using the radiofrequency method, the other is using the newer

¹ Hayashi, Kei. Et al. 1998. *Thermal Modification of Joint Capsule and Ligamentous Tissues*. Operative Techniques in Sports Medicine

² Oratek Manufacturer Packet

electrothermal method. These procedures are gaining popularity as non-surgeons, including physiatrists and anesthesiologists, may perform them.

The occupational nurse consultants have received requests by providers and have asked OMD to review these procedures.

3. FDA Status

Radiofrequency delivery systems by Radionics have had FDA 510 (k) approval since 1991. Both in 1991 and 1998, Radionics corporation received FDA approval to market a RF delivery system, indicated for shrinkage of soft tissue collagen fibers.

Oratek's electrothermal delivery system, SpineCath has been approved as a 510 (k) product since February 1998 for treatment of symptomatic patients with annular disruption of contained herniated discs.

4. Literature Review

No randomly controlled clinical trials have been published in peer-reviewed journals on electrothermal or radiofrequency controlled intradiscal heating.

Radiofrequency

a) Radiofrequency Lesion for Internal Disc Disruption- Methods and design³

A non-published study was performed by Dr. David Salinger involving 29 consecutive patients with discogram positive internal disc disruption who underwent discal radiofrequency of the lumbar spine. The purpose was to create a lesion in the nucleus of the disc to achieve pain relief. Patients were selected on the basis of refusal to have open spinal surgery, they were not deemed a surgical candidate, and if they had a well-hydrated disc on MRI scan. Screening included provocative discography at multiple levels using pressure monitoring and CTR scanning to determine the anatomy of the annulus.

Results

Follow-up was performed for 9 months with results determined by a self-rating of functional capacity, medication use and whether they would consider undergoing the procedure again. After the nine month period of those who had single level lesioning, (n=18), 11/ 18 were off daily medication and back to normal activities, 4/19 were taking reduced medications and back to normal activities and 3/18 were unchanged from before the procedure.

For those who had two level lesions performed (n=8), results were as follows: 4/8 were off daily meds and back to normal activities, 2/8 were taking reduced meds and back to normal activity and 1/3 were unchanged.

³ Salinger, D. 1997. *Radiofrequency Lesion for Internal Disc Disruption*. Online Spinal Injection Newsletter. www.spinalinjection.com/newsletters/nl1997j/radfreq.htm

In the last group, which underwent three level lesions (n=3), the group was evenly divided between the three categories. Follow-up occurred for ten months.

No information was given as to whether patients would choose to undergo the procedure again.

b) Intradiscal Thermal Modulation-Methods and Design⁴

A prospective outcome study was performed on 21 consecutive patients, all of whom had chronic low back pain, from 1-20 years, with an average duration of 6 years. All had undergone conservative treatment trials, including medications, physical therapy, trigger point injections, posterior column sclerosing and epidural injections, with either failure or temporary improvement. Screening included pressure controlled discography, and three pain status assessments. During the procedure tissue was heated to 80 Celsius and a minimum of two lesions were made at 1-2 locations. Average number of discs heated was 2.33 and ranged from 1-5 levels.

Results

Follow-up average length was 9 months and all patients completed the follow-up questionnaires. No complications occurred except for post-operative flare-ups (no number given), on average occurring at 9 days. The mean visual analog pain score was reduced from 7.9 to 5.9, the mean Roland Morris score reduced from 15.52 to 12.9. Fourteen percent felt much better, 52 % better, 33 % the same. Forty seven percent felt that their overall activity improved as a result of the procedure. Despite the improvements, only 10 percent were neutral or satisfied with their overall current level of pain. Eighty one percent requested repeat procedures on the same or adjacent discs because of incomplete pain reduction.

Electrothermal Annuloplasty (IDET)

The Department identified and reviewed documentation on four studies, which discuss the use of electrothermal annuloplasty. Of these, only one is published in a peer-reviewed journal. Three of the four studies were authored by Drs. Saal and Saal, physiatrists who invented and are major shareholders in the Oratek system.

(a) Percutaneous Treatment of Painful Internal Disc Derangement with a Navigable Intradiscal Thermal Catheter-Methods and design⁵

Thirty-one patients were enrolled in a study who met the inclusion criteria which included greater than 6 months lumbar pain, no favorable response to non-operative care, negative SLR, normal neurological exam, no compressive lesion on MRI, no surgery and pain reproduction at low discography (less than 1.25 cc dye volume). All were considered

⁴ Derby, R et al. 1997. *Intradiscal Thermal Modulation*. Presented at the 1997 Annual Meeting of the International Spinal Injection Society.

⁵ Saal, J and J. 1998. *Percutaneous Tx of Painful Internal Disc Derangement with a navigable Intra-discal Thermal Catheter*. Presentation to the North American Spine Society and the American Pain Society

fusion candidates and had declined. Duration of symptoms ranged from 10 months to 11 years. Follow-up had a mean of 27 weeks. Minimum follow-up was 3 months and outcomes were assessed with self-assessment on visual analog pain scores, standardized patient satisfaction and return to work status.

Results

Seventy one percent had at least a 2-point decrease in pain scores on a scale of 2-10 and noted a 2-point increase in sitting tolerance out of a range from 2 to 10. All patients were satisfied with the treatment. Return to work post-procedure occurred in a range from 1-5 days, with analgesics required for 1-3 days

(b) A Novel Approach to Painful Internal Disc Derangement: Collagen Modulation with a Thermal Percutaneous Navigable Intradiscal Catheter-Methods and design⁶

Thirty-six consecutive patients were enrolled in a prospective study. Eleven patients out of this group were enrolled in a pilot study undergoing variable treatments as well as IDET. Inclusion criteria included greater than 6 months lumbar pain, no favorable response to non-operative care, negative SLR, normal neurological exam, no compressive lesion on MRI, no surgery and pain reproduction at low discography (less than 1.25 cc dye volume). All were considered fusion candidates and had declined. Mean duration of symptoms was 54 months. Treatment was with the Oratek SpineCath system. Post-procedure treatment included 6 weeks of exercise followed by 6 weeks of supervised physical therapy.

Results

In the prospective group of 25, which was followed up for a mean of 8.4 months, six patients required a single, short course of corticosteroid treatments for post-op flare-ups. Patients who were working returned in 1-5 day's post-procedure. In this group (n=25), 80 percent of patients improved their visual analog pain scores, with a mean change of 61 percent per patient. Sitting tolerances doubled (no numbers given) and 73% reduced or eliminated analgesics. The group experienced a 72% rate of improvement in pain and function scales (SF-36).

Of the entire 36 patients, 76 % improved on visual analog scores and the entire group nearly doubled their sitting tolerances (no numbers given). Patients with favorable results at 6 months (% not noted) also remained favorable at 11 months.

(c) Intradiscal Electrothermal Annuloplasty-methods and design⁷

A prospective unpublished outcome study done in 1997 looked at 20 patients enrolled in an ongoing pilot investigating long term effects of IDET. Outcomes at 6 months were assessed by examining changes between baseline and 6 month VAS scales and Roland &

⁶ Saal, J. and Saal, J. 1998. A Novel Approach to Painful Internal Disc Derangement: Collagen Modulation with a Thermal Percutaneous Navigable Intradiscal Catheter, A Prospective Trial.

⁷ Derby, R, et al. 1998. *Intradiscal Electrothermal Annuloplasty*. Scientific Newsletter of the Spinal Injection Society.

Morris disability questionnaires. A subjective improvement in activity questionnaire was also utilized on follow-up.

Results

A mean 2-point decrease was noted on the 10 point VAS pain scale, and a 2.2 decrease in disability (not statistically significant). Seventy three percent were satisfied with their outcome, 27% felt the same or worse. Fifty three percent of the group reported improvements in general activity, 73 % in sitting, 46 % in walking. The authors concluded that although the technique looks promising, further study is warranted. The results of their 12-month follow-up will be written as it occurs.

In June of 2000, the department reviewed the following article on IDET to determine if additional evidence has been produced documenting the safety and efficacy of the procedure. This published article is the only new empirical data related to IDET.

(d) Management of Chronic Discogenic Back Pain with a Thermal Intradiscal Catheter. A Preliminary Report⁸

A prospective non-randomized clinical trial. Twenty-five participants were selected from a larger group of patients with chronic low back pain who failed to improve after intensive non-operative treatment. Inclusion criteria consisted of: 1) debilitating low back pain for a minimum of six months (mean approximately five years), 2) non-operative therapies ineffective, 3) normal neurological exam, 4) negative SLR exam, 5) no compressive lesion detected on MRI scan, and 6) concordant pain reproduction with discography. All participants were interbody fusion candidates.

Patient Visual Analog Score (VAS), sitting tolerance times, relevant chart information, and data from pain and function scales (SF-36) were collected after a minimum post-treatment follow-up period of six months. Analysis of variance (ANOVA) software was used on Pre and post-operative data to evaluate outcome variance.

Results

Mean follow-up for the group was seven months (range six to twelve months). Post-operative outcome measures for fifteen patients were obtained at six to nine months and at nine to twelve months in ten patients. Analysis of outcomes failed to show any significant variance. Post-operative recovery consisted of stabilization exercises the first two months; patients had full range of motion by fifth month. Three patients were treated with a single course of oral prednisone; one required an additional injection of corticosteroid.

Twenty patients (80%) reported a reduction in VAS pain scores by at least two points. Mean sitting tolerance for the trial group went from 23.6 minutes pre-treatment to 47.2

⁸ Saal, J. and Saal, J. "Management of Chronic Discogenic Low Back Pain with a Thermal Intradiscal Catheter. A Preliminary Report." ***Spine***, Volume 25, Number 3, pp. 382-388. 2000.

minutes post-treatment. On SF-36 physical function scale, 72% improved by a mean increase of fifteen points. A mean increase of fourteen points on the bodily pain subscale also resulted, a mean change of 48%.

Prior to IDET, nineteen patients were taking narcotic analgesic medications; ten of the nineteen discontinued use and four cut back use by 50% after the IDET procedure. Patients working prior to the procedure returned to work within five days and no adverse effects or worsened conditions resulted in patients following the procedure.

Data Considerations

- Small sample size. This article is preliminary data from 150+/- patient trial being conducted by Rush Presbyterian Hospital (Dr. Andersson) and the University of Chicago (Dr. Wetzel). (Note: Methodology appears to be identical to prior IDET studies conducted by Joel and Jeffery Saal)
- Authors make assertion that IDET outcome measures exceed that of interbody fusion citing secondary data sources/studies with dissimilar methodologies.
- Patient follow-up period too short for assessing the efficacy of procedure.
- Long term consequences of intradiscal thermal treatment with Orthatec catheter unknown. Natural disc degeneration must be factored in too.
- Inconclusive whether or not nerve ingrowth that occurs in disrupted discs will recur after thermal treatment.
- Safety concerns not adequately addressed. Approval of the Oratek SpineCath was “grandfathered” by the FDA since a similar device was on the market prior to passage of the Medical Devices Act. Subsequently, the FDA never assessed safety of the Oratek SpineCath. Authors concur that “long-term consequences of intradiscal thermal treatment with this catheter are not known currently.” Thermal denervation is well documented and has been used for neural lesioning in the brain with radiofrequency needle electrodes. Arthroscopic probes are exempt from FDA pre-market approval.

5. Costs

Oratek, the manufacturer of the electrothermal delivery system and catheter states that the physician’s charge is \$3,800 for the procedure. The spine catheter itself costs \$795. The total cost, according to Oratek, would be \$4,595 for one procedure. However a recent *Newsweek* article stated the procedure cost approximately \$7,000. There would also be costs associated with the recommended six-week course of physical therapy done post-procedure.

6. Professional Organizations

International Spinal Injection Society (ISIS) formally supports this procedure and members have been involved in documenting results from 6 month and 12 month follow up studies.

The North American Spine Society released IDET clinical trial results at their October 1999 conference. Abstracts of these trials are enclosed in Appendix A.

7. Other health insurers positions

As of 6/25/99, the following information was known about coverage of IDET by other insurers.

Workers Compensation programs

Oregon State has heard that this procedure is being performed and has not had any disputes regarding the necessity of this treatment by the insurers. Of other workers compensation programs, Florida and Minnesota were contacted and neither had received requests. Texas WC has authorized this procedure once but has not yet paid for it.

Private insurers

Providence of Oregon says this procedure is not routinely covered and requires prior authorization. Humana was not familiar with the procedure and would send it to their internal medical utilization review board.

8. Conclusion

At this time, no additional evidence has been produced documenting the long term safety and efficacy of intradiscal heating. Safety concerns relating to long term tissue damage have yet to be adequately addressed. Because of this, the department still considers this procedure to be investigational and, therefore, a non-covered health care service.

Appendix A

THERMAL LUMBAR DISC ANNULOPLASTY: INITIAL CLINICAL RESULTS

Philip Mauer, MD, Philadelphia, PA

Goal: Report clinical outcomes on IDET.

Method:

19 Patients

Treatment begun in June, 1998

“Discogenic” low back pain, little or no leg pain

“Poor response” to conservative treatment

Absent “significant” psychological factors

“Screened with MRI and/or plain x-rays to evaluate disc pathology”

“Positive discography” at “low pressure”

All were “candidates for surgical intervention of discectomy or fusion”

Procedure:

IDET per manufacturer’s protocol

28 lumbar discs treated

11 patients at single level

7 patients at 2 levels

1 patient at 3 levels

Evaluations

3 weeks, 3 months, 6 months post-IDET

VAS, SF-36, functional tolerance, spine ROM

Results:

Decreased pain (change in VAS Score) at Follow Up

<u>Improvement from baseline</u>	<u>3 weeks (n = 19)</u>	<u>3 months (n = 14)</u>	<u>6 months (n = 7)</u>
Very Good to Excellent (60 – 100%)	3 (16%)	6 (43%)	6 (86%)
Good (40 – 60%)	8 (42%)	1 (7%)	0
Fair (20 – 40%)	2 (10%)	4 (29%)	0
No change (<20%)	6 (32%)	3 (21%)	1 (14%)

Improved Function at Follow Up [not further defined]

Level of Improvement	<u>3 weeks (n = 19)</u>	<u>3 months (n = 14)</u>	<u>6 months (n = 7)</u>
Very good to Excellent (60 – 100%)	3 (16%)	2 (14%)	6 (86%)
Good (40 – 60%)	3 (16%)	5 (36%)	0
Fair (20 – 40%)	6 (32%)	4 (29%)	0
No change (<20%)	7 (36%)	3 (21%)	1 (14%)

Conclusions: IDET “is safe, effective and an attractive alternative to patients for the treatment of back pain as a consequence of internal disc disruption. Further studies that document the healing of the annular collagen and longer term data are warranted.”

**INTRADISCAL ELECTROTHERMAL ANNULOPLASTY (IDET) FOR
CHRONIC DISC DISEASE: OUTCOME ASSESSMENT WITH MINIMUM ONE
YEAR FOLLOW-UP**

Joel S. Saal, MD; Jeffrey A. Saal, MD, SOAR, physiatry Medical Group, Menlo Park, CA

Goal: "...assess the outcome of a larger cohort of patients with longer-term follow-up to evaluate the potential efficacy of [IDET]".

Method: 60 patients met inclusion criteria which included
Lumbar pain of at least 6 months duration
No favorable response to comprehensive non-operative care
Normal neurological examination
Negative SLR
MRI with no neural compressive lesion
No previous surgery at the index treatment level
Pain reproduction with provocative discography at <1 cc dye volume
Mean duration of symptoms greater than 1 year
All patients were considered fusion candidates (all offered fusion; all declined)
IDET
Pre- and post-procedure SF-36, VAS, sitting tolerance & medication usage reports

Results: 71% "improved"
29% "unchanged"
1 patient underwent fusion during the study period
Mean follow-up was 14 months
No neurological deficits or infectious complications

Conclusion: "The present study demonstrates that the improvement in pain and function at 6 month follow-up in initial clinical studies persists in follow-up approaching one year. IDET is an effective treatment option for chronic discogenic low back pain."

A CONTROLLED TRIAL OF THE EFFICACY OF INTRA-DISCAL ELECTROTHERMAL TREATMENT FOR INTERNAL DISC DISRUPTION

*Michael Karasek, MD; Dennis Karasek, MD; Nikolai Bogduk, MD, PhD, Northwest Spine
Group, Eugene, OR; Newcastle Bone and Joint Institute, Newcastle, Australia*

Goal: Evaluate the efficacy of IDET

Method: From 140 patients presenting with chronic low back pain 2/98 to 10/98, 53 met IASP diagnostic criteria for internal disc disruption. The 53 had accustomed pain reproduced by stimulation of the affected disc, without pain with stimulation at adjacent level; at least grade III annular tear on CT.

36 underwent IDET

17 denied permission by insurance company (control group). Control therapy: PT regimen to which all patients would have been subjected, had IDET not been available

Measurements: VAS, Oswestry disability score, drug consumption
Administered at baseline, 2 wks, 6-8 wks and 12 wks “after treatment”

Results: Control group:

Resolution of pain: 1 patient
Improved ~ 20%: 2 patients
Same or worse: 14 patients

IDET group

Before treatment, mean VAS = 8.0

After treatment, mean VAS = 3.6 through 12 weeks of follow-up

50% of patients had reduction of 5 on the 10-point scale utilized

90% of patients had a reduction of at least 3 on same scale

26 patients had some relief

Mean VAS was 2.7

53% of patients achieved a VAS of 2 or less

“Reduction in VAS correlated with concomitant reduction in use of opioids and improvements in Oswestry scores.

4 patients had no relieve of pain

Conclusion: Efficacy of IDET “appears to be better than that of conservative care” for IDD. “Factors such as operator enthusiasm, and the placebo effect of a new and sophisticated treatment have not been excluded. That requires a randomized, double-blind, controlled trial. The results of the present study provide the necessary estimates of the putative efficacy of IDET, on the basis of which a controlled study with appropriate power can now be designed.”

**INTRADISCAL ELECTROTHERMAL ANNULOPLASTY (IDET) TREATMENT
FOR CHRONIC MULTI-LEVEL DISCOGENIC PAIN: PROSPECTIVE 1 YEAR
FOLLOW-UP OUTCOME STUDY**

Jeffrey A. Saal, MD; Joel S. Saal, MD SOAR, Physiatry Medical Group, Menlo Park, CA

Goal: Prospective evaluation of “the outcome of a consecutively identified group of patients which chronic pain due to two and three level disc derangement who were treated with the IDET procedure and followed for a minimum period of one year.”

Method: 29 patients
Consecutively identified from authors’ clinical practice
Suffering from chronic disabling lumbar pain for at least 1 year
Failed all attempts at nonoperative care, including
Exercise-based physical therapy;
NSAID’s;
Epidural corticosteroid injection
Facet joint injection;
Corsets;
Chiropractic care;
Activity and job modification
MRI scans revealed no evidence of neurocompressive lesions
MRI scans demonstrated 2- or 3-level disc dessication
With or without high intensity zones
With or without focal disc protrusions
Discogram reproduced concordant pain
Less than 1.25 cc injectate, at
2 or 3 lumbar levels
2 patients had fusions at levels adjacent to index levels
4 patients had previous disectomies at the index level
Administered pre- and post-treatment
VAS
SF-36
Sitting tolerance reports

Results: 29 patients treated
7 at 3 lumbar levels
22 at 2 lumbar levels
15 female; 14 male
“65% of the total group improved 3 points or more” on the VAS
“71% of the patients with three level disc derangement improved their VAS scores a minimum of 3 points”
“67% of the total group improved their sitting tolerance time by a factor of 2”
“SF-36 scores on the physical function & bodily pain subscales improved 66% of the total group, and 5/7 of the 3 level cases.”

“No patient suffered a neurologic injury, infection or worsening of his or her clinical condition.”

Conclusion: “IDET...successfully treated 71% of patients with multilevel disc derangement, as measured by VAS and 66% as measured by SF-36 after a minimum follow-up analysis period of one year.” IDET is safe and effective treatment for 2 and 3 level disc derangement.